

Attorney Docket No.: PM (DC-0251)
Inventor: Wade and Demian
Serial No.: 09/720,078
Filing Date: July 25, 2001
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REMARKS

Claims 1, 2, 5, and 8-17 are pending in the instant application. Claims 1, 2, 5, and 8-17 have been rejected. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims Under 35 U.S.C. §103

The rejection of claims 1, 2, 5 and 8-17 under 35 U.S.C. §103(a) as being unpatentable over Anand et al. (U.S. Patent No. 6,291,208) and Heath (U.S. Patent Application No. 2002/0135722) and further view of Applicants' admission that species of classes and types of antigens are held obvious in view of one another in the instant invention has been maintained. The Examiner suggests that Anand et al. teach the use of antibody conjugates comprising antibodies that bind antigen presenting cells, including dendritic cells, to deliver antigens in order to generate immunogenic compositions to a variety of antigens and that this is applicable to any antigen derived from viruses, bacteria and tumors. It is further suggested that Heath teaches the co-administration of a CD40 stimulating moiety (e.g., anti-CD40 antibodies) and the appropriate antigen, including the use of covalent linkage or co-entrapment as a vaccine to a variety of antigens. Thus, the Examiner suggests that prior art teaches all three components of the composition used in accordance with the method of the invention. It is suggested that adjuvants are substances that enhance or potentiate the immune response to an antigen and that Heaths that CD40 stimulators can enhance antibody response to pneumococcal polysaccharides in individuals unable to respond to polysaccharide only-based vaccines. It is

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therefore, suggested that there would be a reasonable expectation of success in producing an immune response greater than the simple sum of antibody-antigen conjugates and anti-CD40 antibodies acting alone. The Examiner suggests that given the teachings of Heath to provide anti-CD40 with antigen in composition form or as a conjugate and the teachings of Anand et al. to provide antigen with anti-antigen present cell/dendritic cell antibodies, it would have been obvious to one of ordinary skill in the art to administer the antigen in the context of such antigen-antibody conjugate with the immunostimulatory anti-CD40 antibodies to boost the immune response to a wide variety of desired antigens, including providing both components in the same compositions, as taught by Heath. It is further suggested that one of ordinary skill would have been motivated to target professional antigen presenting cells such as dendritic cells with the combination of antigen-antibody targets and the immunostimulatory agonistic CD40 antibodies to enhance the immune response to a wide variety of antigens. The Examiner suggests that Applicants arguments in the reply dated June 13, 2005 are not persuasive because Applicants have argued against the references individually rather than their combination and that one cannot show non-obviousness by attacking references individually. Applicants respectfully disagree with the Examiner's conclusions.

MPEP 2143.01 indicates that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). To address the issue of the

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desirability of the combination each reference must first be considered individually in order to determine if either alone, or when combined, the desirability of the combination is suggested. In the case at hand, either alone, or when combined, the references cited by the Examiner fail to suggest the desirability of combining the cited references and, in fact, one of the references (Anand et al.) teaches away from the instant invention and thus cannot contribute at all to the desirability of the combination of references.

Anand et al. specifically teach at column 3, lines 3-5, that "[o]ne feature of the present invention is the ability to obtain an enhanced immune response to an antigen without the use of an adjuvant." From this passage and the disclosure as a whole, in particular column 9 which discusses vaccine preparation and use, it is clear that Anand et al. do not contemplate the use of an adjuvant in combination with antigen-antibody conjugate disclosed therein.

In contrast, Heath specifically identifies CD40 ligands as adjuvants for eliciting an immune response to antigens (see paragraphs 0044-0046).

Accordingly, there would be no motivation to modify the teachings of Anand et al. to routinely include a CD40 adjuvant of Heath, because Anand et al. fail to suggest the desirability of the combination in stating that an enhanced immune response is obtained "without the use of an adjuvant". Thus, the suggestion or motivation to modify Anand et al. or to combine the referenced teachings is lacking and therefore the claimed invention is not obvious in accord with the requirement set forth in MPEP 2142.

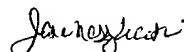
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The same issue of lack of desirability for combining references is found if one carefully looks at the reference of Heath et al. This reference teaches use of adjuvants and as such would not be combined with a reference that states that adjuvants are not a necessary part of a method for stimulating an immune response. Clearly, one of skill would not look to combining these two references as neither reference would provide the desirability for such a combination. It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

II. Conclusion

The Applicants believe that the foregoing comprises a full and complete response to the Advisory Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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